

June 17, 2013

Michael E. Gans  
Clerk of the Court  
United States Court of Appeals for the Eighth Circuit  
Thomas F. Eagleton U.S. Courthouse  
111 South 10th Street  
St. Louis, Missouri 63102

Re: *United States ex rel. Laurie Simpson v. Bayer Healthcare et al.*,  
No. 12-2979: Response to Appellant's 28(j) Letter

Dear Mr. Gans,

Pursuant to Federal Rule of Appellate Procedure 28(j), Appellees respectfully respond to Appellant's June 14th letter informing the Court of the United States' Statement of Interest in *United States ex rel. Krahling v. Merck & Co.*, No. 10-CV-4374 (E.D. Pa.).

Contrary to Appellant's contentions, the Statement of Interest is irrelevant to the issues in this case. That Statement responded to Merck's specific legal argument that the complaint in that case "must be dismissed because 'suits by private citizens—as distinguished from the [G]overnment—may not be premised either on a manufacturer's fraud on the FDA or on a contention that a manufacturer has violated an FDA regulation.'" (Ex. 2 at 2.)

This appeal raises no question about Appellant's standing to allege particular legal theories. It concerns whether Appellant has pled her theories sufficiently to satisfy the requirements of Rules 8 and 9(b). She has not. *See* Appellees' Br. 29–36. Moreover, Appellant is not pursuing a fraud-on-the-FDA theory and has nowhere alleged with particularity that Bayer fraudulently induced the FDA to take particular actions. Indeed, she acknowledges that the FDA knew of numerous matters at issue in her complaint. *See* SAC ¶¶ 136.b, 152–61, 168, 184 (A-49–A-145). And, as for her regulatory-noncompliance allegations, Bayer has argued that these claims fail because she has not alleged the elements of materiality, causation, and representative false claims with the particularity required by Rule 9(b).

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Nothing in the Statement of Interest addresses these issues or purports to allow Appellant to satisfy Rule 9(b) by merely invoking the term “misbranding” without more. *See* Appellees’ Br. 30–31, 33–35.<sup>1</sup>

Very truly yours,

A handwritten signature in black ink, appearing to read 'A. L. Hoeflich', with a stylized flourish at the end.

Adam L. Hoeflich

*Counsel for Appellees*

cc: Edward Normand, Esq. (via ECF)

*Attorney for Relator-Appellant*

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<sup>1</sup> The settlement agreement referenced in Appellant’s Letter (Exhibit 3) is likewise irrelevant. Indeed, the DOJ’s position in another case is not evidence of when government payors would have refused payment for Baycol.